UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte LEWIS T. WILLIAMS, JAIME ESCOBEDO, MICHAEL A. INNIS, PABLO DOMINGUEZ, JULIE SUDDUTH-KLINGER, CHRISTOPH REINHARD, KLAUS GIESE, FILIPPO RANDAZZO, GIULIA C. KENNEDY, DAVID POT, ALTAF KASSAM, GEORGE LAMSON, RADOJE DRMANAC, RADOMIR CRKVENJAKOV, MARK DICKSON, SNEZANA DRMANAC, IVAN LABAT, DENA LESHKOWITZ, DAVID KITA, VERONICA GARCIA, LEE WILLIAM JONES and BIRGIT STACH-CRAIN

Appeal No. 2005-0125
Application No. 09/313,292

ON BRIEF

Before WILLIAM F. SMITH, SCHEINER and GRIMES, Administrative Patent Judges.

SCHEINER, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the final rejection of claims 123 through 130, the only claims remaining in the application.

According to appellants, the polynucleotides of claims 123-126 and 128-130 "have a defining feature of a polynucleotide sequence of at least 150 contiguous nucleotides of SEQ ID NO: 972 or complement thereof[,]" while the polynucleotides of claim 127 "have a defining feature of a polynucleotide sequence of an insert of a vector

deposited at the American Type Culture Collection . . . which contains a polynucleotide having the sequence set forth in SEQ ID NO: 972" (Brief, page 19). SEQ ID NO: 972 is a 300 base pair cDNA corresponding to a partial mRNA transcript from a human colon cancer cell line (Specification, page 43, lines 32-35, and page 45, lines 17-20). According to appellants, polynucleotides comprising SEQ ID NO: 972 or portions thereof "may be used to detect nucleic acids that are expressed at higher levels in cancerous cells as compared to non-cancerous cells" (Brief, page 7).

Claims 123 and 127 are representative of the subject matter on appeal:

123. An isolated polynucleotide comprising at least 150 contiguous nucleotides of a sequence selected from SEQ ID NO: 972 and a complement of SEQ ID NO: 972.

127. An isolated polynucleotide comprising a nucleotide sequence of an insert contained in a clone deposited as clone number M00007118B:B04 of ATCC Deposit Number PTA-60.

DISCUSSION

Claims 123-130 stand rejected under the first paragraph of 35 U.S.C. § 112, as lacking adequate written description.

As discussed above, SEQ ID NO: 972 is a 300 base pair cDNA corresponding to a partial mRNA transcript from a human colon cancer cell line – it is something less than a full length cDNA. Specification, page 43, lines 32-35, and page 45, lines 17-20. The examiner notes that "claims 123-130 encompass full length cDNA comprising SEQ ID NO: 972, genomic sequences that hybridize to SEQ ID NO: 972, and vectors and host cells comprising full length cDNA comprising SEQ ID NO: 972" (Answer, page 4). "With the exception of SEQ ID NO: 972" (id.), the examiner's position is that "[n]one of these sequences meet the written description provision of 35 [U.S.C. §] 112, first paragraph" (id.) because "the skilled artisan cannot envision [their] detailed chemical structure" (id.).

According to the examiner, an "[a]dequate written description requires more than a mere statement that [a species encompassed by the claims] is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required" (id.).

Appellants concede that "[a]ll of the appealed claims are written in open form. That is, they employ the claim transition phrase 'comprising.' . . . As such, any of the nucleic acids encompassed by the appealed claims may contain nucleic acid residues flanking the 5' and/or the 3' ends of the recited identifying polynucleotide sequence" (Brief, page 10). "[W]hile the full-length cDNA to which SEQ ID NO: 972 corresponds is encompassed by the claims, . . . [it] is but one species of the polynucleotides encompassed by the claimed genus" (id., page 11), and, moreover, would be a "later-invented species of Appellants' generic invention" (id., page 34).

Appellants argue that "there is no basis for [the written description] rejection" "[s]ince there is no requirement that every species of a claimed genus be specifically described . . . in order to satisfy 35 U.S.C. § 112, ¶ 1" (id., page 11), or that "every conceivable and possible future embodiment" be described (id., page 34). Appellants assert that "[t]he evidentiary record establishes that the [ ] specification describes the claimed invention so that one skilled in the art can recognize what is claimed" and it "describe[s] a representative number of species within [the] recited genus of polynucleotide molecules to permit one of skill in the art to 'visualize or recognize members of the genus'" (id., pages 51-52).

"The 'written description' requirement serves a teaching function, . . . in which the public is given 'meaningful disclosure in exchange for being excluded from practicing the invention for a limited period of time.'" University of Rochester v. G.D. Searle & Co., Inc., 358 F.3d 916, 922, 69 USPQ2d 1886, 1891 (Fed. Cir. 2004) (citation omitted).

Another "purpose of the 'written description' requirement is . . . [to] convey with reasonable clarity to those skilled in the art that, as of the filing date [ ], [the applicant] was in possession of the invention." Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). See also Enzo Biochem Inc. v. Gen-Probe Inc., 296 F.3d 1316, 1329, 63 USPQ2d 1609, 1617 (Fed. Cir. 2002). The requirement is satisfied when the specification "set[s] forth enough detail to allow a person of ordinary skill in the art to understand what is claimed and to recognize that the inventor invented what is claimed." University of Rochester, 358 F.3d at 928, 69 USPQ2d at 1896. Whether or not a specification satisfies the requirement is a question of fact, which must be resolved on a case-by-case basis (Vas-Cath, 935 F.2d at 1562-63, 19 USPQ2d at 1116), and it is the examiner's "initial burden [to] present[ ] evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims" (In re Wertheim, 541 F.2d 257, 263, 191 USPQ 90, 97 (CCPA 1976)).

"[A]pplicants have some flexibility in the 'mode selected for compliance' with the written description requirement" (University of Rochester, 358 F.3d at 928, 69 USPQ2d at 1896); it is well settled that actual reduction to practice is not necessary to satisfy the requirement (id., at 926, 69 USPQ2d at 1894). In University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997), the court discussed the application of the written description requirement to inventions in the field of biotechnology, stating that "[a] written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." Id. at 1567, 43 USPQ2d at 1405. The court also stated that

> a generic statement such as 'vertebrate insulin cDNA' or 'mammalian insulin cDNA,' without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is.

Id. at 1568, 43 USPQ2d at 1406. The court concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material" (id.), but "[a] description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." Id.

Here, all of the polynucleotides in the claimed genus have a common structural feature – all contain at least a portion of SEQ ID NO: 972 or its complement. That the polynucleotides may additionally contain flanking sequences (or other moieties) does not change that. The specification provides at least one specific example of a polynucleotide containing flanking sequences in addition to SEQ ID NO: 972 – clone number M00007118B:B04 of ATCC Deposit Number PTA-60 – and describes several others in general terms. For example, the specification teaches that the claimed polynucleotides can be "flanked by one or more nucleotides with which [they are] not normally associated on a naturally occurring chromosome[;]" and they "can be provided within autonomously replicating molecules (vectors) or within molecules without replication sequences" and their expression "can be regulated by their own or by other

regulatory sequences known in the art (Specification, page 5). Similarly, the specification teaches that SEQ ID NO: 972 can serve as the basis for various types of probes, which "can be labeled . . . with a radioactive, biotinylated, or fluorescent tag" (id.).

In addition, appellants rely on the declaration of Dr. Christopher R. Somerville,[1] in which Dr. Somerville offers his expert opinion that "[t]he overall disclosure of the specification demonstrates that there is no criticality to sequences flanking the polynucleotides of the Invention" and "[t]he Skilled Person would readily appreciate from the specification that the sequence of SEQ ID NO: 972 can be incorporated within a vast number of larger polynucleotides, and that each of these sequences is identifiable as having at least 150 contiguous nucleotides of SEQ ID NO: 972" (Somerville Declaration, ¶ 17). Dr. Somerville states, for example, that "a Skilled Person would recognize that a probe may contain polylinker sequences, or an oligonucleotide 'tail'" (id., ¶ 13); and that "a Skilled Person, by performing a simple sequence comparison . . . between SEQ ID NO: 972 and any given nucleotide would have been able to straightforwardly determine whether a given polynucleotide fell within any one of the claims" (id., ¶ 20). Again, as explained in Lilly, a genus of polynucleotides can be described by a representative number of polynucleotides, defined by sequence, or sharing common structural features which constitute a substantial portion of the genus. Moreover, as explained in University of Rochester, 358 F.3d at 928, 69 USPQ2d at 1896, the written description requirement is satisfied when the specification "set[s] forth enough detail to allow a person of ordinary skill in the art to understand what is claimed and to recognize that the inventor invented what is claimed."

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[1] Declaration executed September 27, 2002; first submitted September 27, 2002.

Whether the level of disclosure in the specification would have allowed one skilled in the art to recognize that the inventor invented what is claimed is a question of fact. The USPTO has summarized a number of factors to be considered in making this determination; they include "the level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention." Guidelines for Examination of Patent applications Under the 35 U.S.C. § 112, ¶ 1, "Written Description" Requirement, 66 Fed. Reg. 1099, 1106 (Jan. 5, 2001). "Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." Id.

In responding to the rejection, appellants addressed several of these factors, relying on the specification as filed, and on the Somerville Declaration. The examiner has not questioned the objective truth of any of the factual evidence in the record, nor has the examiner questioned Dr. Somerville's qualifications as an expert or his stated opinion that "[t]he Skilled Person would readily appreciate from the specification that the sequence of SEQ ID NO: 972 can be incorporated within a vast number of larger polynucleotides, and that each of these sequences is identifiable as having at least 150 contiguous nucleotides of SEQ ID NO: 972" (Somerville Declaration, ¶ 17). Rather, the examiner has focused exclusively on the fact that "SEQ ID NO: 972 [ ] is less than the full length cDNA" (Answer, page 3) in asserting that "one of skill in the art could not know that the applicants had possession of a representative number of species of the claimed genus at the time of filing" "[b]ecause a large number of species of the claimed

genus of polynucleotides, vectors, and cells have sequences that are not fully described" (id., page 6).

This conclusory statement is insufficient to meet the examiner's initial burden of establishing that one skilled in the art would not have recognized that appellants were in possession of what is claimed. Accordingly, the rejection is reversed.

REVERSED

William F. Smith
Administrative Patent Judge

Toni R. Scheiner
Administrative Patent Judge

Eric Grimes
Administrative Patent Judge

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